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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,030	03/17/2004	Patrick Benoit	08888.0530-01	3970

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EXAMINER	
GIBBS, TERRA C	

ART UNIT	PAPER NUMBER
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/802,030	BENOIT ET AL.	
	Examiner	Art Unit	
	TERRA C. GIBBS	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *20 and 21* is/are withdrawn from consideration.

5)☒ Claim(s) *8* is/are allowed.

6)☒ Claim(s) *1-6,15, 17, and 18* is/are rejected.

7)☒ Claim(s) *7,9-14,16 and 19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Sequence Alignments #1 and #2*.

DETAILED ACTION

This Office Action is a response to Applicant's Amendment and Remarks filed April 10, 2008.

Claims 1-21 are pending in the instant application.

Claims 1, 8, and 16 have been amended.

Claims 20 and 21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 8, 2006.

Applicant is reminded that the Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Accordingly, claims 1-19 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

In the previous Office Action mailed February 22, 2004, claims 1-6, 15, and 17-19 were rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/65924 ('924). **This rejection is withdrawn** in view of Applicant's Remarks filed April 10, 2008.

Specifically, the Examiner is withdrawing this rejection in view of Applicant's Remarks that, based on hybridization standards taught by the Molecular Cloning Manual (1989) the fragments disclosed by '924 would not hybridize to the claimed sequences.

However, after careful reconsideration of the claims, a new ground(s) of rejection is presented as detailed below:

Claim Objections

Claims 16 and 17 are objected to because of the following informalities: Claim 16 has a period and a comma after "SEQ ID NO:2" in line 11. It appears that the period is either misplaced or is an inadvertent mistake. Appropriate correction is required.

Claim 17 is missing a period at the end of the claim. Appropriate correction is required.

Priority

Applicant's reference to priority in the first sentence of the specification is acknowledged. However, the reference should be updated to reflect applications for patents that have issued.

Applicant is reminded that the instant invention has been afforded priority to March 17, 2004, which is the filing date of the instant application because support for claims drawn to an isolated polynucleotide comprising SEQ ID NO:3 or a fragment of SEQ ID NO:3, wherein said fragment comprises a) nucleotide 594 to nucleotide 2740

(SEQ ID NO:4), b) nucleotide 691 to nucleotide 2740 (SEQ ID NO:5), c) nucleotide 1159 to nucleotide 2740 (SEQ ID NO:6), d) nucleotide 1930 to nucleotide 2740 (SEQ ID NO:7), or e) a sequence that hybridizes after three washes at 65° C in the presence of 0.2x SSC, and 0.1% SDS with any one of SEQ ID NOs: 3 to 7, wherein said polynucleotide in the absence of inverted terminal repeat sequences from adeno-associated virus specifically induces expression in cardiac cells *in vivo* of a gene which is operably linked to said polynucleotide provided that said polynucleotide does not comprise nucleotides 2053 to 2074 of SEQ ID NO:2 cannot be found in any parent application(s) for which Applicants claim priority to.

If Applicants believe that they are entitled to an earlier priority date, the Examiner urges Applicant to specifically point, with particularity, where support can be found for the instant claims in any prior applications Applicants claim priority to.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 15, 17, and 18 are rejected under 35 U.S.C. 102(e) as being

anticipated by U.S. Patent No. 7,250, 496 ('496).

Claims 1-6 are drawn to an isolated polynucleotide comprising SEQ ID NO:3 or a fragment of SEQ ID NO:3, wherein said fragment comprises a) nucleotide 594 to nucleotide 2740 (SEQ ID NO:4), b) nucleotide 691 to nucleotide 2740 (SEQ ID NO:5), c) nucleotide 1159 to nucleotide 2740 (SEQ ID NO:6), d) nucleotide 1930 to nucleotide 2740 (SEQ ID NO:7), or e) a sequence that hybridizes after three washes at 65° C in the presence of 0.2x SSC, and 0.1% SDS with any one of SEQ ID NOs: 3 to 7, wherein said polynucleotide in the absence of inverted terminal repeat sequences from adeno-associated virus specifically induces expression in cardiac cells *in vivo* of a gene which is operably linked to said polynucleotide provided that said polynucleotide does not comprise nucleotides 2053 to 2074 of SEQ ID NO:2. Claims 15 and 17-19 are dependent on claim 1 and include all the limitations of claim 1 with the further limitations wherein the polynucleotide comprises a vector; wherein the vector is a plasmid; and wherein the vector is derived from adenovirus.

'496 discloses nucleic acid molecules encoding 20600 GAM genes and 6635 GR genes, wherein the nucleic acid molecules are vectors and probes comprising the nucleic acid molecules (see Abstract, for example). Specifically, '496 discloses:

> "[A]ccordingly, the invention provides several substantially pure DNAs (e.g., genomic DNA, cDNA or synthetic DNA) each encoding a novel gene of the GAM group of gene, vectors comprising the DNAs, probes comprising the DNAs" (see Summary of the Invention)
>
> "[B]y "substantially pure DNA" is meant DNA that is free of the genes which, in the naturally-occurring genome of the organism from which the DNA of the invention is derived, flank the genes discovered and isolated by the present invention. The term therefore includes, for example, a recombinant DNA which is incorporated into a vector, into an

autonomously replicating plasmid or virus" (see Summary of the Invention)

It is noted that '496 discloses, for example, SEQ ID NO:91361, which is a 26mer sequence that is fully complementary to nucleotides 716-741 of SEQ ID NO:7 of the instant invention (see attached sequence alignment #1). Since SEQ ID NO:91361 of the '496 application is fully complementary to SEQ ID NO:7 of the instant invention, given this high degree of similarity, the nucleic acid molecule disclosed by the '496 application meets the structural limitations of the claimed invention and would be expected to hybridize after three washes at 65°C in the presence of 0.2x SSC and 0.1% SDS with a sequence of SEQ ID NOs: 3-7, absent evidence to the contrary.

The burden of establishing whether the prior art nucleic acid molecule has the further function of specifically inducing expression in cardiac cells *in vivo* of a gene which is operably linked to the nucleic acid molecule under generally any assay conditions as instantly claimed falls to Applicant. See (*In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977): "Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an Applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product... Whether the rejection is based on 'inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products [footnote omitted]. See also MPEP 2112: "[T]he PTO can require an Applicant to prove that the prior art products do not

necessarily or inherently possess the characteristics of his [her] claimed product." The MPEP at 2122 citing *In re Fitzgerald* 205 USPQ 594. 596, (CCPA 1980), quoting *In re Best* 195 USPQ 430 as per above. Also, see *In re King*, 801 F.2d 1324, 1327, 231 USPQ 136, 139 (Fed. Cir. 1986). Therefore, it falls to Applicant to determine and provide evidence that prior art nucleic acid molecules disclosed by the '496 application would or would not have the additional functional limitation of specifically inducing expression in cardiac cells *in vivo* of a gene which is operably linked to the nucleic acid molecule under generally any assay conditions.

Therefore, absent evidence to the contrary, '496 anticipates claims 1-6, 15, 17, and 18 as claimed.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank Accession No. AQ480395, unpublished in 1997. GenBank entry created in April, 1999.

Claim 1-6 are as described above.

GenBank Accession No. AQ480395 discloses a human clone sequence that is almost fully complementary to nucleotides 1-244 of SEQ ID NO:7 of the instant invention (see attached sequence alignment #2). Since GenBank Accession No. AQ480395 is nearly fully complementary to SEQ ID NO:7 of the instant invention, given this high degree of similarity, the sequence disclosed by GenBank Accession No. AQ480395 meets the structural limitations of the claimed invention and would be expected to hybridize after three washes at 65°C in the presence of 0.2x SSC and 0.1% SDS with a sequence of SEQ ID NOs: 3-7, absent evidence to the contrary.

The burden of establishing whether the prior art sequence has the further function of specifically inducing expression in cardiac cells *in vivo* of a gene which is operably linked to the sequence under generally any assay conditions as instantly claimed falls to Applicant. See (*In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977): "Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an Applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product… Whether the rejection is based on 'inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products [footnote omitted]. See also MPEP 2112: "[T]he PTO can require an Applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [her] claimed product." The MPEP at 2122 citing *In re Fitzgerald* 205 USPQ 594. 596, (CCPA 1980), quoting *In re Best* 195 USPQ 430 as per above. Also, see *In re King*, 801 F.2d 1324, 1327, 231 USPQ 136, 139 (Fed. Cir. 1986). Therefore, it falls to Applicant to determine and provide evidence that prior art sequence disclosed by GenBank Accession No. AQ480395 would or would not have the additional functional limitation of specifically inducing expression in cardiac cells *in vivo* of a gene which is operably linked to the sequence under generally any assay conditions.

Therefore, absent evidence to the contrary, GenBank Accession No. AQ480395

anticipates claims 1-6 as claimed.

Conclusion

Claims 7, 9-14, and 19 are objected to as being dependent upon a rejected base claims, but would be allowable if rewritten in independent form to include all of the limitations of the base claim and any intervening claims. Claims 7 and 9-14 are considered to be free of the prior art since the prior art does not teach or fairly suggest an isolated polynucleotide comprising SEQ ID NO:3 or a fragment of SEQ ID NO:3, wherein said fragment comprises a) nucleotide 594 to nucleotide 2740 (SEQ ID NO:4), b) nucleotide 691 to nucleotide 2740 (SEQ ID NO:5), c) nucleotide 1159 to nucleotide 2740 (SEQ ID NO:6), d) nucleotide 1930 to nucleotide 2740 (SEQ ID NO:7), or e) a sequence that hybridizes after three washes at 65° C in the presence of 0.2x SSC, and 0.1% SDS with any one of SEQ ID NOs: 3 to 7, wherein said polynucleotide in the absence of inverted terminal repeat sequences from adeno-associated virus specifically induces expression in cardiac cells *in vivo* of a gene which is operably linked to said polynucleotide provided that said polynucleotide does not comprise nucleotides 2053 to 2074 of SEQ ID NO:2, wherein the polynucleotide comprises an expression cassette comprising a sequence encoding a protein or an RNA of therapeutic interest operably linked to the polynucleotide; wherein the vector further comprises an origin of replication which is active in cardiac cells; and a composition comprising a therapeutically effective amount of the vector comprising the polynucleotide and a pharmaceutically acceptable carrier.

Allowable Subject Matter

Claims 8 is allowable. Claim 8 is allowable since the prior art does not teach or fairly suggest an expression cassette comprising SEQ ID NO:9 and a sequence encoding a protein or an RNA of therapeutic interest operably linked to an isolated polynucleotide comprising SEQ ID NO:3 or a fragment of SEQ ID NO:3, wherein said fragment comprises a) nucleotide 594 to nucleotide 2740 (SEQ ID NO:4), b) nucleotide 691 to nucleotide 2740 (SEQ ID NO:5), c) nucleotide 1159 to nucleotide 2740 (SEQ ID NO:6), d) nucleotide 1930 to nucleotide 2740 (SEQ ID NO:7), or e) a sequence that hybridizes after three washes at 65° C in the presence of 0.2x SSC, and 0.1% SDS with any one of SEQ ID NOs: 3 to 7, wherein said polynucleotide in the absence of inverted terminal repeat sequences from adeno-associated virus specifically induces expression in cardiac cells *in vivo* of a gene which is operably linked to said polynucleotide provided that said polynucleotide does not comprise nucleotides 2053 to 2074 of SEQ ID NO:2.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James “Doug” Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

July 31, 2008
/Terra Cotta Gibbs/